Amendment #1 (Questions & Responses) to RFP-NIH-NIAID-DAIDS-03-26

"Regulatory Compliance Center"

Amendment to Solicitation No.:	NIH-NIAID-DAIDS-03-26
Amendment No.:	1
Amendment Date:	May 22, 2002 (Questions 1 - 2) July 1, 2002 (Questions 3 – 22)
RFP Issue Date:	March 29, 2002
Issued By:	Barbara A. Shadrick bs92y@nih.gov Senior Contracting Officer CMB, NIAID, NIH 6700-B Rockledge Drive Room 2230, MSC 7612 Bethesda, Maryland 20892-7612
Point of Contact:	Nancy Hershey nh11x@nih.gov Contracting Officer
Name and Address of Offeror:	To All Offerors

THE HOUR AND DATE SPECIFIED FOR RECEIPT OF OFFERS IS NOT EXTENDED AND REMAINS AT JULY 15, 2002, 4:00 PM, EST.

OFFERORS MUST ACKNOWLEDGE RECEIPT OF THIS AMENDMENT #1 ON EACH COPY OF THE OFFER SUBMITTED. FAILURE TO RECEIVE YOUR ACKNOWLEDGMENT OF THIS AMENDMENT MAY RESULT IN THE REJECTION OF YOUR OFFER.

THIS AMENDMENT PROVIDES QUESTIONS SUBMITTED BY OFFERORS AND THE RESPONSES PROVIDED BY THE NIAID PROJECT OFFICER. ANY FURTHER QUESTIONS AND THEIR RELATED RESPONSES WILL BE ADDED TO THIS AMENDMENT UPON RECEIPT. ALL OFFERORS SHOULD REFER BACK TO THIS AMENDMENT #1 FOR ADDITIONAL QUESTIONS AND RESPONSES.

Below are the Questions and Responses issued on May 22, 2002:

Question 1 In reference to Page 46, Exhibit J.4.1., Key Personnel, clarification of the phrase "or equivalent" in the statement regarding section J.4.1.l., "the Project Manager shall possess a Ph.D., or equivalent." Can experience be substituted for the degree; if not, what academic fields and degrees will be acceptable.

Examples of acceptable degrees include Dr., Ph.D., D.N.Sc., ScD, EdD, etc., with the emphasis in a scientific area of expertise and past FDA experience with IND/NDA clinical trials. Either FDA experience with IND/NDA studies (preference) or clinical trial management experience in the field where IND trials are involved.

Question 2 In reference to Page 46, Exhibit J.4.2., Other Key Personnel (Non-Key), clarification of the statements regarding sections, J.4.2.5 and J.4.2.6., that all Health analysts, Health Coordinators and Health Specialists be Registered Nurses (R.N.). We recognize that certain task functions, most notably adverse event management, must be performed by clinically trained personnel, however, the designations of analyst, specialist, and coordinator are applied to personnel in other task areas, such as regulatory affairs and study registration. Is it your intent to require that all professional staff in all task areas be registered nurses?
No. All Professional staff do not have to be RNs, and scientific degrees are acceptable, diversity is encouraged as long as the personnel have clinical trials research experience.

Below are the Questions and Responses issued on July 1, 2002:

Question 3 What is the staffing level by labor category on the existing contract?
The existing contract has been staffed by 25-30 FTEs; and currently, approximately 6 people are part-time ranging from 3% - to 50% full-time.

Question 4 Provide an inventory and location of any government furnished equipment (GFE)?
The following GFE is located at the current Contractor: a LAN server, a Database/SQL Server, Colorado External Tape Drive, 20 Computer Workstations, Xerox model FAX machine, HP Laser Printer, and Borland Interbase for NTS.

Question 5 Please provide functional (i.e., functions supported) and technical details (i.e., hardware, software, operating systems, interface capabilities, users supported) of the existing Management Information System. Is the MIS Government or Contractor owned? Does the Government see the systems requested for "establishment" in C.2.4. and C.2.5. as replacements for existing systems or enhancements?
The existing MIS system consists of Microsoft Windows NT, Microsoft SQL Server and a Delphi system. The functions supported are listed in the RFP-Section C: Task Areas A-J. The MIS and Tracking System is Contractor-owned and, therefore, the Government would require replacements for existing systems and possibly some enhancements.

Question 6 Do all extramural data centers (page 7) use the same data transmittal system to obtain information from DAIDS?
No, the extramural data centers use various transmittal systems to collect and provide data to DAIDS via the current Contractor.

Question 7 Do the serious adverse experience (SAE) reports come in only in English?
YES.

Question 8 Will DAIDS international regulatory training be in English?
Yes, all training will be in English, since we operate within the context of US regulations. We could provide training in Spanish and possibly other languages if needed for special circumstances.

Question 9 Does DAIDS consider submitting electronic INDs? If yes, are there a document management system (Documentation, etc.) and an electronic Submission Management System (CoreDossier, EZ-Subs, etc.) in place at DAIDS?
No, DAIDS is not currently considering electronic submission of INDs.

Question 10 Will DAIDS provide access to scientific and information databases (i.e. MEDLINE, etc.) for IND preparation?
No. DAIDS will be unable to provide direct access.

Question 11 Will IND relating meetings with FDA, companies, etc., organized by the Contractor, be held at DAIDS or the Contractor's site?
Most IND-related meetings are actually conference calls. Face-to-face meetings are usually held at DAIDS.

Question 12 Is there a system in place at DAIDS that warehouses information regarding DAIDS-sponsored clinical trials (i.e., accrual information)?
The current Contractor produces a weekly clinical trials accrual and status report to DAIDS. The accrual data for this report is sent to the Contractor by the data management centers and other data is in house.

Question 13 Please explain regulatory review (section C.2.3.2. and C.2.3.3). Will the Contractor be required to provide formal legal opinion on DAIDS related regulatory issues?
C.2.3.2. Regulatory review in this section of the RFP means that the Contractor, in conjunction with the DAIDS Human Subjects Protection Specialist, or designee, will perform review of the Protocol Specialist sample informed consent to verify that the consent form meets all applicable regulatory requirements in addition to all DAIDS required policies. No formal legal opinion will be required of the Contractor. C.2.3.3. – Regulatory review in this section of the RFP means that the Contractor, as the DAIDS Regulatory Affairs Branch (RAB) designee, will review all Site Specific IRB approved consent forms against the protocol specific sample informed consent forms against the protocol specific sample informed consent to verify its accuracy with the above-mentioned items.

Question 14 What level of effort is expected under section C.2.3.7. (i.e., the provision of information and materials or also expert advice?).
The Contractor should be familiar with the DAIDS Informed Consent template, Informed Consent Requirements from 45 CFR 46, specifically subpart B (which was recently revised 12/31/01) since many of our studies assess the prevention of HIV transmission from mother to infant. DAIDS RAB will provide the final regulatory approval of all Informed Consent forms.

Question 15 Please explain the requirement to "provide medical assessment" of SAEs (sections C.2.5.1)?. Is the Contractor expected to provide a formal medical opinion to DAIDS?
This requirement means the Contractor is to summarize the SAE info provided to them by the sites. The summaries are then forwarded to DAIDS medical officers and to our Safety Specialist. No formal medical opinion is required by the Contractor, but it must have medical expertise to be able to properly evaluate the quality of the info provided by the sites. For example, the Contractor may have to follow-up with the sites to check on lab or autopsy results, or if the SAE form is missing critical information.

Question 16 Please describe the existing "central database of each DAIDS network" section C.2.5.6.).
DAIDS currently works with 3 statistical centers, which in turn support our various networks through a Cooperative Grant mechanism. One center uses an INGRES database with a UNIX operating system and SAS statistical software; another center uses UNIX plus a DATAFAX (vers 3.5) and DATAMAN-a SAS based data management system. The last center uses UNIX based system running on SUN workstations. Their database management system uses Oracle with NOMAD (a 4th generation DBMS) as a front end. Statistical analyses are performed mainly in SAS and other packages like S + are used for specialized analyses.

Question 17 Please explain the term "capsules" in section C.2.6.1.1.
The term capsule refers to a short (2-3 page) summary of a proposed research project.

Question 18 What level of effort is expected under section C.2.7.2? Will the Contractor be required to provide formal legal opinion on DAIDS-related contractual matters?
DAIDS RAB currently obtains legal opinion when needed. For clinical trials agreements (CTAs), the Contractor will be expected to maintain standard templates for all the DAIDS networks and facilitate, support and track the negotiations/communications, which are required to develop these agreements. Examples of tasks include scheduling conference calls, checking with companies and DAIDS regarding the status of the agreements, etc. The Contractor will also be expected to interact with other NIAID groups to ensure the consistency of these contracts.

Question 19 Will the Contractor be required to provide storage space for DAIDS documents such as INDs, clinical site reports, CRFs, etc.? If so, will the Contractor be required to provide a fireproof storage facility for these documents?
Yes to both questions. Periodically, the CRFs will be transported to the government's local storage site where CRFs are kept for a period of 25 years.

Question 20 What level of effort is expected under Section C.2.10.7? Will the Contractor be required to provide formal medical and legal opinion on DAIDS funded protocols?
No formal medical or legal opinion will be required of the Contractor on DAIDS funded protocols. The purpose of the full regulatory reviews of the final protocols and their amendments is to verify that all required DAIDS specified sections of the final protocols and their amendments is to verify that all required DAIDS specified sections of the protocol are complete and congruent with all other sections. The purpose of the informed consent regulatory review on final protocols is to verify the items as described in the response to question 11 (see previous question and response); and to ensure that the Informed Consent is consistent with protocol specific requirements.

Question 21 For costing purposes, you asked us to estimate a portfolio of 120 INDs and 400 protocols active or in development. Can you please state what percentage of the 120 INDs are active?
At any one time, 95-120 INDs are active and an equal number are inactive; and a relatively small number (5%) are in development.

Question 22 Will government equipment (i.e., computers) be transferred from the predecessor contract, or will we need to price computers separately that will be necessary to perform the work under the new contract award?
Government-furnished property will be transferred from the predecessor contract although it is noted that these computers are over three years old.

[END OF AMENDMENT #1]